AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92689

U.S. Appln. No.: 10/567,565

REMARKS

This Amendment is filed in response to the non-final Office Action dated April 24, 2008,

and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly,

favorable reconsideration on the merits and allowance are respectfully requested.

In the present Amendment, Claim 55 has been amended to recite "[a]n amide derivative

of formula (I) or a salt thereof." The claim has been amended to improve its form by deleting the

recitation "may have a substitutent(s)," as suggested by the Examiner, and inserting the recitation

"a substituted or unsubstituted." Support for these claim amendments can be found in the

original specification on pages 11-18, for example.

Claim 57 has been amended to correct clerical errors with respect to misspelled

nomenclature of moieties listed in the R³ group.

Claim 65 has been canceled.

Claim 66 has been amended to recite "a method for treating herpes virus infection". No

new matter has been added.

Claims 1-54 were previously canceled without prejudice.

Entry of the Amendment is respectfully submitted to be proper. Upon entry of the

Amendment, claims 55-64 and 66 will be all the claims pending in the application.

I. Response to Double Patenting Rejection

Claims 55-66 are rejected on the ground of non-statutory obviousness-type double

patenting as being assertedly unpatentable over claims 1-9 of U.S. Patent No. 6,903,125.

9

U.S. Appln. No.: 10/567,565

Applicants respectfully request that the rejection be withdrawn in view of Applicants' submission of a Terminal Disclaimer, concurrently filed herewith.

II. Response to Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as assertedly failing to comply with the enablement requirement.

Applicants respectfully traverse and request that the rejection be withdrawn in view of the amendments to the claims, and further in view of the following remarks.

Claim 66 has been amended, as recommended by the Examiner, to recite: "A method of treating a herpes virus infection." The method according to Claim 66 comprises administering to a patient in need of such treatment, a therapeutically effective amount of an amide derivative or a salt thereof of Formula (I), according to Claim 55. Claim 55 is directed to the compound of Formula (I):

$$\mathbb{Z}$$
 \mathbb{A}
 \mathbb{A}
 \mathbb{A}
 \mathbb{A}
 \mathbb{A}
 \mathbb{A}

The compound of Formula (I) is not broad in scope because the core is a heterocyclic substituted phenyl carbamoyl methyl amide/sulfamide and the substitutions on the core are minimal. Furthermore, the heterocyclic substituted phenyl carbamoyl methyl amide/sulfamide core is known in the art to have pharmaceutical utility as anti-varicella zoster virus (VZV) and anti-cytomegalovirus (CMV) agents. (See, specification at pages 2-4, formulae (G) and (H); see

also, Patent references 1, 2 and 3 on page 5). Thus, these classes of compounds are known to treat herpes viral related disorders.

Additionally, Applicants' disclosure meticulously provides references to show that amide and sulfamine derivatives have anti-HSV-1 and anti-CMV activity. VZV causes varicella and herpes zoster, and CMV is an infectious disease caused by herpes viruses. (See, specification at page 1, lines 12-21). The specification teaches that the prior art compounds, the compound in formula (G) and (H), which are thiazole-phenyl carbamoylmethyl amide/sulfamide derivatives, are known to have anti-VZV and anti-CMV activity.

Next, the present specification further provides pharmacological tests to confirm anti-VZV and anti-HSV activity of the compound of formula (I) in present Claim 55. (See, specification at page 32-37). Thus, there is sufficient guidance and working examples in the specification to enable one skilled in the pertinent art to make or use the compound of Formula (I) to treat herpes viruses without undue experimentation.

Additionally, claim 66 does not recite a mechanism of action to render the claim as a "reach through" claim. Accordingly, claim 66 does not lack enablement and is not a "reach through claim". Withdrawal of the rejection is requested.

III. Response to Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 55-66 are rejected under 35 U.S.C. § 112, second paragraph, as being assertedly indefinite. Particularly, the Examiner asserts that the phraseology "may have a substituent(s)" in claim 55^2 and claims depending therefrom renders the claim indefinite. Next, the Examiner

indicates that there are a few typographical errors in claim 57 with respect to variable R³. Lastly,

the phrase "disease in which herpes virus is involved" is assertedly indefinite.

Applicants traverse.

Claims 57 and 66 have been amended to improve their claim form. Claim 55 has been

amended to recite "substituted or unsubstituted" with respect to the various moieties and Claim

66 has been amended to recite a method of treating herpes virus infection. **Applicants**

respectfully submit that the amendment overcomes the rejection.

Furthermore, the amendment to claim 55 is proper and, the claim, as amended, is definite.

Under the guidance of the M.P.E.P., Applicants may define a variable as being a substituted or

unsubstituted moiety, so long as one skilled in the art could interpret the metes and bounds (i.e.,

scope) of the claim so as to avoid infringement. In the specification on page 13, Applicants

clearly define what is meant by "substituent(s)". Thus, the claim clearly sets forth what

Applicants regard as their invention and the claims particularly point out and define the metes

and bounds of the invention. Accordingly, Applicants request that the rejection be withdrawn.

IV. Response to Claim Objections

Claim 55 is objected to because of the recitation of "general formula (I)", and claim 65 is

objected to as being a substantial duplicate of claim 64.

The Examiner referred to claim 1 in the Office Action. We believe that the Examiner

inadvertently referenced claim 1 instead of claim 55.

12

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92689

U.S. Appln. No.: 10/567,565

Applicants respectfully request that the objection be withdrawn in view of the

amendments to Claim 55, which deletes the objected-to phraseology, and the cancellation of

Claim 64.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

Brett S. Sylvester

Registration No. 32,765

SUGHRUE MION, PLLC

Telephone: (202) 293-7060

Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565

CUSTOMER NUMBER

Date: July 24, 2008

13